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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,830	01/08/2002	Gary E. Borodic	33677-00000	2713

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/040,830	Applicant(s) BORODIC ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED _____ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on *20 December 2004*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see Supplemental Advisory Action*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *16-19*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Supplemental Advisory Attachment.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 12/20/04
13. ☒ Other: Interview Summary (3/8/05).

Supplemental Advisory Action Attachment

1. Applicant's amendment filed December 20, 2004 is acknowledged and Telephonic interview held March 8, 2005 (see attached Interview Summary).

2. Applicants amendment is not entered because the claims as amended would require further consideration and require new searches. As amended the claims are directed to a method of treating facial pain caused by trigeminal neuralgia comprising administering to a patient in need thereof multiofocal injection a therapeutically effective amount of botulinum toxin to an afflicted area of the face of said patient thereby reducing or eliminating said facial pain caused by trigeminal neuralgia. The previous claims were directed a method of treating facial pain caused by trigeminal neuralgia. However, there was no limitation in the claims regarding a specific type of administration (e.g. multifocal injection) nor was there a limitation in the claims regarding a specific afflicted area in which the botulinum toxin should be administered (e.g. the face). Therefore, the scope of the claimed invention has changed by the newly added limitations and these limitations were not the subject of the searches in the previous Office actions. The claim limitations as amended have not been search or considered before the submission of the After Final Amendment. These new claim limitations would require new art rejections.

Rejections Maintained

3. The Applicant's arguments regarding the rejection of claims 16-19 under 35 U.S.C. 102(e) were addressed on pages 2-4, paragraph 4 of the Final Office Action.

4. The Applicant's arguments regarding the rejection of claims 16-19 under 35 U.S.C. 102(e) were addressed on pages 4-6, paragraph 5 of the Final Office Action.

The rejection was on the grounds that Binder teaches a method of treating pain caused by trigeminal neuralgia by delivering an invertebrate presynaptic neurotoxin (botulinum toxin A) to a mammal (see the Abstract). Binder teaches that the botulinum toxin A is administered to the muscles of the face, cranium and neck (see the Abstract). Binder teaches that neurotoxin can be administered in a dose up to about 1000 units although individual dosages of about 15-30 units are preferred and dosages of 2.5 to 5 units will have therapeutic efficacy. Binder teaches that the neurotoxin will be administered as a composition at a dosage that is proportionally equivalent to about 2.5 cc/100 units (see columns 5-6). The claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because trigeminal neuralgia is associated with trauma and pain. Binder anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that nothing in Binder anticipates or renders obvious the presently pending claims because there is no teaching or suggestion anywhere in Binder of the claimed method for treating facial pain caused trigeminal neuralgia. Applicant urges that post herpetic neuralgia is not trigeminal neuralgia and the two are recognized as being distinct by those skilled in the art. Applicant urges that pain caused

by trigeminal neuralgia is an accepted distinct clinical syndrome with unique diagnostic criteria and etiology (causes). Applicant urges that one skilled in the art would not confuse facial pain caused by trigeminal neuralgia with other states associated with pain. Applicant urges that health care professional recognize that there are different diagnostic criteria in regard to trigeminal neuralgia, migraine and tension headaches.

Applicant's arguments filed May 28, 2004 and telephonic interview held March 8, 2005 have been fully considered but they are not persuasive. The claims are directed to a method of treating facial pain caused by trigeminal neuralgia comprising administering to a patient in need thereof a therapeutically effective amount of botulinum toxin to an afflicted area of said patient, thereby reducing or eliminating said facial pain caused by trigeminal neuralgia. Webster's II New Riverside University Dictionary defines "trigeminal neuralgia" as an intensively painful inflammation of the facial area around the trigeminal nerve. Stedman's Medical Dictionary, 24th Edition defines "trigeminal nerve" as the fifth cranial nerve. Binder teaches that trigeminal neuralgia is associated with cranial and facial nerves and trigeminal neuralgia is also commonly associated with headaches *Table 1(b), column (2). Binder teaches a method of alleviating pain from local areas of the face including relief of headache as well as such trigeminal neuralgia by administration of botulinum toxin (column 6, lines 58-67 and column 7, lines 1-3). Table 1(b) (column 2). Binder teaches a therapeutically effective amount of neurotoxin (botulinum toxin) is administered by extramuscular injection to the perimuscular areas of the face, cranium and neck (column 4). Binder teaches that reduction of headache pain was unexpectedly observed even in patients

whose pain was causally related to vascular or neurological components; e.g., classical migraine, trigeminal neuralgia and trauma headache (column 6, lines 58-67 and column 7, lines 1-3). Therefore, one skilled in the art would recognize that botulinum toxin can be used to treat headaches as well as trigeminal neuralgia since trigeminal neuralgia is caused by inflammation of cranial nerves and Binder et al teaches that additional therapeutic benefits can be expected from administration of the presynaptic neurotoxin of the invention into one or more striated muscles of the face, cranium and/or neck (column 4) To address Applicant's comments regarding the diagnostic distinction between trigeminal neuralgia, migraine and tension headaches, the art recognizes that theses disorders are distinct one from the other however, Binder teaches that botulinum toxin can be used to treat any of these disorders column 6, lines 58-67 and column 7, lines 1-3). There is nothing on the record to show that the claimed method differs from that of the prior art. Therefore, the teachings of Binder anticipates the claimed method.

Status of Claims

5. No claims are allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
March 19, 2005

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